Battery Council International

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HAND DELIVERY

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Ms. Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Petition for Modification of Hazard Ranking System Regulations

Dear Ms. Browner:

This is a petition for modification of the Environmental Protection Agency's (EPA) Hazard Ranking System (HRS) regulations. It is submitted in accordance with Section 4(e) of the Administrative Procedure Act, 5 U.S.C. §553(e) (1994). The petition is submitted on behalf of the Battery Council International (BCI) and its members.[1]

SUMMARY

This petition seeks modification of the HRS human toxicity factor (HTF) value for lead codified at 40 C.F.R.§ 300 App. ¶ 2.4.1.1. The current HTF value for lead (10,000) does not reflect accepted scientific knowledge about the toxicity of lead and provides no quantitative consideration of lead toxicity or risks. As such, the current HTF value violates the express mandate of Congress that the HRS "assure, to the maximum extent feasible, that the hazard

[1] BCI is a not-for-profit trade association representing commercial entities involved in the manufacture, distribution, sale and recycling of lead-acid batteries. BCI's members include manufacturers and distributors of lead-acid batteries and the secondary smelters that reclaim or recycle lead batteries once they are spent. BCI's membership represents more than 99 percent of the nation's domestic lead battery manufacturing capacity and more than 90 percent of the nation's recycling or secondary smelting capacity.

ranking system accurately assesses the relative degree of risk to human health and the environment posed by sites and facilities subject to review." Section 105(c)(1) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 42 U.S. C. § 9605(c)(1) (1994).

Reanalysis of the HTF value for lead conducted in accordance with accepted scientific principles and knowledge about the toxicity of lead and EPA's standard approach to lead risk assessment shows that the HTF value should be revised to no greater than 1,000. *See* Gradient Corporation, *A Critical Evaluation of U.S. EPA's Hazard Ranking System Score Calculated for Lead,* (Jan. 1998) [hereinafter "Gradient Report"] attached as App. A. *See also* Testimony of Barbara D. Beck on behalf of BCI before the Environmental Engineering Committee of the EPA Science Advisory Board (Apr. 29, 1997) attached as App. B.

It is extremely important that the Agency move expeditiously on this petition for rulemaking. This is because use of the current HTF value for lead inappropriately ranks hazardous waste sites under the HRS. This often results in the inclusion on the National Priorities List (NPL) of less hazardous sites that exhibit lead contamination in the place of sites that pose a greater threat to human health and the environment due to contamination from other hazardous substances. Moreover, EPA's use of the current HTF value for lead in other programs, such as the Sector Facility Indexing Project, which ranks facilities on the basis of Toxic Release Inventory data multiplied by an HRS-derived toxicity weighting factor, further exacerbates this bias.

DISCUSSION

A. Background

The HRS is a scoring system used by EPA to assess the relative threats associated with actual or potential releases of hazardous substances from a site. An HRS score is determined for a site by evaluating several migration routes or "pathways," such as water, air, and soil, along with the toxicity of the substances at a site, waste quantity, and the risks to nearby populations to yield a pathway score. The pathway scores are then combined according to a mathematical formula to produce the HRS score for a site. *See* 53 Fed. Reg. 51962 (Dec. 23, 1988). A score of 28.5 or greater results in a site being listed on the NPL.[2] *See Tex Tin Corp. v. EPA,* 935 F.2d 1321, 1323-24 (D.C. Cir. 1991).

EPA proposed the current version of the HRS in 1988. 53 Fed. Reg. 51962 (Dec. 23, 1988). The public comment period on the proposal ended on February 21, 1989. The final HRS was published on December 14, 1990, and took effect on March 14, 1991. 55 Fed. Reg. 51532 (Dec. 14, 1990).

As promulgated in 1990, the HRS evaluates the risk posed by a compound in part by considering the HTF value assigned to that compound. The HTF value is based upon a compound's quantitative dose-response parameters. Those parameters are the compound's acute lethal dose (LD_{50}), chronic reference dose (RfD), and cancer slope factor (SF), as calculated at the time a site is being scored. *See* HRS ¶ 2.4.1.1.

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[2] Listing a site on the NPL has serious and far-reaching consequences. *See Kent County v. EPA*, 963 F.2d 391, 394 (D.C. Cir. 1992). A site's placement on the NPL is likely to result in considerable costs being incurred for environmental investigative studies and associated activities to clean up contamination identified by those studies. Moreover, a site's listing on the NPL could damage the business reputation of the owner and diminish the value of the property. *Id.* at 394.

Where there is no available quantitative dose-response parameter for a particular compound, the HRS assigns to that compound a HTF value of zero. Further, if all the compounds evaluated at a particular site have a HTF value of zero, the overall HTF value for the site is set at 100. HRS ¶ 2.4.1.1.

The sole exceptions to the foregoing procedures are for asbestos and lead (and its compounds). For these compounds, the HRS automatically assigns a HTF value of 10,000. No consideration is given to scientific understanding of the toxicity of these substances at the time of scoring. Indeed, no specific regard is given to the appropriate LD_{50}, RfD or SF. HRS ¶ 2.4.1.1.

The automatic use of the 10,000 HTF value for lead (and its compounds) was not employed in any earlier version of the HRS, and was not included in the proposed rule or otherwise made publicly available for comment. The first public indication regarding this HRS provision was when EPA included it in the final HRS.

In an internal memorandum placed in the record immediately before final HRS promulgation (but long after the public comment period had expired), EPA justified its decision to assign the maximum HTF value to lead as follows:

> A RfD was not developed for lead because the concept of threshold (i.e., a dose level exists below which adverse health effects will not occur) is a critical assumption implicit to the RfD and the data seem to suggest that a threshold may not exist for the neurological effects resulting from lead exposure. . . . Lead is assigned the maximum toxicity value of 10,000 for scoring purposes in the revised HRS for the following reasons: the absence of a demonstrated threshold for systematic toxicity; the cumulative sequestration of lead in the bone matrix and its subsequent release during pregnancy or osteoporosis; and the absence of an RFD [sic.] and a cancer factor would give lead a toxicity factor value of 0

under the revised HRS which is inconsistent with known health effects.[3]

By inserting the automatic use of the 10,000 HTF value into the HRS rule without allowing public comment, EPA violated basic tenets of both the Administrative Procedure Act, 5 U.S.C. § 553(c), and CERCLA. CERCLA § 105(c)(1) expressly required EPA to issue the HRS only "after publication of notice and opportunity for submission of comments in accordance with section 553 of Title 5, . . ." Moreover, as discussed below and in the attached report by Gradient Corporation, the automatic use of the 10,000 HTF value for lead also is inconsistent with accepted scientific knowledge about the toxicity of lead and EPA's standard approach for lead risk assessment.

B. EPA's Rationale for the Current HTF Value Fails to Reflect Accepted Scientific Knowledge about the Toxicity of Lead, Provides No Quantitative Consideration of Lead Toxicity or Risks, and Is Inconsistent with the Agency's Standard Approach for Lead Risk Assessment

EPA's rationale for assigning lead a HTF value of 10,000 fails for several reasons. In the words of Gradient Corporation "it does not reflect accepted scientific knowledge about the toxicity of lead and provides no quantitative consideration of lead toxicity or risks. Assigning lead the arbitrary toxicity factor value of 10,000 ignores EPA's standard approach for lead risk assessment . . ." Gradient Report at 20. As such, the current HTF value violates the express mandate of Congress that the HRS "assure, to the maximum extent feasible, that the hazard ranking system accurately assesses the relative degree of risk to human health and the environment posed by sites and facilities subject to review." 42 U.S. C. § 9605(c)(1).

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[3] Memorandum of Larry J. Zaragoza, Site Assessment Branch, to the HRS Docket, Nov. 9, 1990 (attached as Ex. 1 to Beck testimony).

The essence of HTF values is that they allow quantitative comparison across chemicals. Selection of the highest value available based upon qualitative evidence will lead to inappropriate decisionmaking and undesirable outcomes. This can be seen in Table 3-1 of the Gradient Report, which compares lead with cadmium, a metal that bioaccumulates to an even greater degree than lead, and with PCBs, a class of chlorinated aromatic compounds, which cause cancer in rodents. Thus, both cadmium and PCBs exhibit characteristics similar to those described in the 1990 EPA memo assigning lead a HTF value of 10,000, namely bioaccumulation and possible lack of a threshold.

Table 3-1 shows that EPA's HTF values for cadmium and PCBs are 1,000, one-tenth that of lead. When these values are compared to EPA soil screening levels (risk-based concentrations) for all three chemicals, there is an even greater discrepancy. The soil screening level for lead is 400 parts per million (ppm), much higher than that for cadmium (39 ppm) or PCBs (1 ppm) despite the fact that lead has a higher HTF value than either cadmium or PCBs.

This result makes no sense. If lead is more toxic than cadmium and PCBs, its soil screening levels should be lower than both, not higher. EPA's soil screening levels illustrate that the toxicity of lead is approximately 10 percent of the toxicity of cadmium, and 0.25 percent the toxicity of PCBs. But the HRS HTF values would indicate that lead's toxicity exceeds the toxicity of both cadmium and PCBs by a factor of 10. As Gradient Corporation states "it is clear that the HRS toxicity factor value substantially overstates the toxicity of lead." Gradient Report at 9.

Moreover, as the Gradient Report makes clear, EPA's concerns over the lack of a demonstrated threshold for systematic toxicity, the cumulative sequestration of lead in the bone matrix and its subsequent release during pregnancy or osteoporosis, and its concern that in the

absence of an RfD or SF lead would be assigned a value of zero, are a scientifically inadequate base for the selection of a HTF value. This is because first, in the words of Gradient Corporation, "evidence of lead's influence below 10 μg/dl is ambiguous at best. RfD [values] for many other substances are not *known* adverse effect thresholds. . . . Because of the uncertainty associated with the calculation of RfDs for many other substances, it is often impossible to determine the true value of an adverse effect threshold, or whether an effect threshold exceeding zero even exists". Gradient Report at 18-19.

In fact, EPA explicitly recognized this principle when revising the current HRS. In the proposed rule, EPA defined RfD "as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The determination of the RfD requires scientific judgments as to the appropriate NOAEL (No Observed Adverse Effect Level), uncertainty factors, and modifying factors. . . . Similarly, while the RfD is seen as a level at which the probability of adverse effects is low, the absence of risk to all people cannot be assured at this level." 53 Fed. Reg. 51971.

Second, with regard to lead in the bone matrix and the possibility of release during pregnancy or osteoporosis, although "[t]his phenomenon may occur, . . . it is not relevant to the determination of an HRS toxicity factor value. . . . The HRS toxicity factor value depends only on a substance's RfD or its cancer slope factor and weight-of-evidence category. That is, *only a substance's impact on health is relevant in the determination of its HRS toxicity factor value.* EPA does not consider sequestration or body residence time in the case of other substances. For example, the fact that many other substances, such as PCBs, are sequestered in the body's lipotissue indefinitely is not relevant to the determination of their HRS toxicity factor values. Moreover, consideration of body residence time would lead to irrational score assignments. For

example, like lead, fluoride is also incorporated into bone tissue (tooth enamel), and thus presumably remains in the body indefinitely. Fluoride can also be toxic at sufficiently high doses. Nonetheless, it would not make sense to assign to fluoride the highest possible HRS toxicity factor value solely because it can cause adverse health effects and because it remains in the body indefinitely. As with other substances, EPA should consider only the maximum acceptable daily intake for lead, and not whether lead remains in the body for an extended period." Gradient Report at 19.

Finally, with regard to the Agency's concern that in the absence of a RfD or SF lead would be assigned a HTF value of zero, Gradient Corporation states "the fact that assigning a toxicity factor value of 0 to lead might lead to results EPA opposes does not justify assigning the highest possible HRS toxicity factor value to this substance." *Id.* Assigning the highest HTF value to lead is patently inconsistent with EPA's HRS regulations that require EPA to assign a toxicity factor value of zero "if neither an RfD, nor slope factor, nor acute toxicity value is available, . . ." HRS ¶ 2.4.1.1.

"In summary, EPA's reasoning is an inadequate basis for the selection of a human toxicity factor value. . . . Use of HRS scores for lead specified as part of EPA's 1990 rule defining the HRS, inappropriately ranks potentially hazardous waste sites, leading to the inclusion on the NPL of less hazardous sites that exhibit lead contamination in the place of sites that pose a greater threat to human health due to contamination by other substances." Gradient Report at 20.

In fact, had EPA used its standard approach for lead risk assessment when calculating the HTF value for lead, it would have assigned lead a value that is at least ten times less than the current value. EPA's standard approach to lead risk assessment is to predict the distribution of

blood lead levels in the population of concern and to compare the prediction with health-based criteria for blood lead levels. Children represent the primary population of concern for lead. In this case, EPA uses the Integrated Exposure Uptake Biokinetic (IEUBK) Model to estimate blood lead levels. The IEUBK Model estimates the intake and uptake of lead into the body and then uses pharmacokinetic modeling to predict blood lead levels.[4]

Since 1990, the IEUBK Model has been extensively used by the Agency to assess risks of exposure from lead and its compounds. For example, the agency's Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities (Revised Interim Soil Lead Guidance) specifically states that "[t]he residential screening level for lead described in this directive has been calculated with the Agency's new Integrated Exposure Uptake Biokinetic Model (IEUBK) model (Pub. # 9285.7-15-2, PB93-963511), using default parameters." Memorandum of Elliott P. Laws, Assistant Administrator, to EPA Regional Administrators, *Revised Interim Soil Lead Guidance for CERLCA Sites and RCRA Corrective Action Facilities,* at 2 (Jul. 14, 1994). That guidance also states that "[t]his model was developed to: recognize the multimedia nature of lead exposures; incorporate important absorption and pharmacokinetic information; and allow the risk manager to consider the potential distributions of exposure and risk likely to occur at a site. . . . Use of the IEUBK model in the context of this guidance will allow risk managers to assess the contribution of different environmental sources of lead to overall blood lead levels . . ." *Id.* at 2-3.

The guidance further states that "[t]he Agency believes that the IEUBK Model is the best available tool currently available for assessing blood lead levels in children". *Id.* at 5. The

[4] It should be noted that BCI does not endorse EPA's IEUBK Model. As discussed in Section 5.2 of the Gradient Report, BCI believes that the IEUBK Model is far too conservative in predicting the distribution of blood lead levels among populations of children at Superfund sites. Nonetheless, the Agency relies heavily on the model.

Agency also has used the IEUBK Model to evaluate the National Ambient Air Quality Standards (NAAQS) for lead,[5] and to evaluate and establish lead soil standards under Section 403 of the Toxic Substances Control Act.[6]

EPA's risk management decisions for lead are based on setting an environmental lead concentration that protects a significant portion of the most sensitive population. In the case of lead, the target is for 95 percent of all children to have blood lead concentrations equal to or less than 10 μg/dl.[7] As EPA explained in its Revised Interim Soil Lead Guidance "[d]evelopment of the residential screening level in this interim directive required two important OSWER [Office of Solid Waste and Emergency Response] decisions. 1) OSWER determined that it would seek to achieve a specific level of protectiveness in the site cleanups; generally, OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5 percent of exceeding the 10 μg/dl blood lead level. This 10 μg/dl blood lead level is based upon analyses conducted by the Centers for Disease Control and EPA that associate blood lead levels of 10 μg/dl and higher with health effects in children. *Revised Interim Soil Lead Guidance* at 8.

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[5] *See* Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency *Review of National Ambient Air Quality Standards for Lead: Exposure Analysis Methodology and Validation* (Research Triangle Park, NC 1989).

[6] *See* Memorandum of Doreen Cantor, Office of Pollution Prevention & Toxics, to Section 403 Dialogue Participants (Nov. 5, 1997).

[7] The target of 10 μg/dl blood derives from the 1991 Centers for Disease Control (CDC) statement on lead poisoning in young children. *See* Centers for Disease Control, U.S. Department of Health and Human Services *Preventing Lead Poisoning in Young Children* (Oct. 1991). The value of 10 μg/dl represents a threshold level of concern. It is not an intervention level, either medial or environmental. The CDC recommends that children with blood lead levels between 10-14 μg/dl should be monitored more frequently.

C. Calculation of HFT Value Using EPA's IEUBK Model

In the absence of the automatic assignment of a 10,000 HTF value for lead, lead-containing sites would be subject to the same types of calculations as sites containing other constituents. Under the HRS, a RfD for lead toxicity would be established. As explained in Section 5.1 of the Gradient Report, utilizing EPA's IEUBK model to establish the HTF value based on a target of 95 percent of the children having blood leads less than 10 μg/dl, yields an RfD of 2×10^{-3} mg/kg/day. Using a RfD of 2×10^{-3} mg/kg/day results in a HFT value of 1,000. HRS ¶ 2.4.1.1.

Recognition of the 2×10^{-3} mg/kg/day RfD is particularly appropriate since, as the Gradient Report indicates, that dose level was implicitly adopted by EPA in developing its residential soil screening levels. Those levels were specifically designed by EPA to achieve a specific level of protectiveness such that a typical child or group of similarly exposed children would have an estimated risk of no more than 5 percent of exceeding the 10 μg/dl blood lead level. Moreover, it should be further recognized that the 2×10^{-3} mg/kg/day RfD was calculated using overly conservative default assumptions. Thus, it errs on the side of conservatism and, as discussed below, is likely to overestimate the RfD for lead by an order of magnitude.

D. Alternative HTF Value for Lead

Section 5.2 of the Gradient Report explains how EPA's IEUBK Model overstates blood lead levels corresponding to a specific level of lead exposure. Section 5.2 compares IEUBK Model predicted blood lead levels with site-specific blood lead levels collected from children living near several sites that have undergone investigations and are now being cleaned up under the CERCLA program. When these site-specific data are compared to the IEUBK Model

predictions, it is clear that the IEUBK Model substantially overstates the risk of lead exposure on children's blood lead levels.

In fact, as Gradient states "use of a more neutral blood lead prediction model might yield an even lower HRS toxicity factor value for lead." Gradient Report at 14. A HTF value of 100 appears more appropriate in certain situations where lead is relatively unbioavailable. Data from CERCLA sites in Aspen, Colorado; Leadville, Colorado; Butte, Montana; Bingham Creek, Utah; Palmerton, Pennsylvania; and Granite City, Illinois support the choice of 100 as an appropriate value.

E. As a Matter of Law EPA Must Revise Its HTF Value

As this petition demonstrates, EPA's continued reliance upon the current HTF value for lead (10,000) does not reflect accepted scientific knowledge about the toxicity of lead and provides no quantitative consideration of lead toxicity or risks. As such, it violates the express mandate of Congress that the HRS "assure, to the maximum extent feasible, that the hazard ranking system accurately assesses the relative degree of risk to human health and the environment posed by sites and facilities subject to review." 42 U.S. C. § 9605(c)(1). As the D.C. Circuit recognized, where continued compliance with a statutory standard is questioned, an agency "cannot sidestep a reexamination of" the regulation after receiving a petition under APA § 553(e), 42 U.S.C. § 553(e). *Geller v. FCC,* 610 F.2d 973, 979 (D.C. Cir. 1979). Rather, it has "an affirmative duty" to "determine whether [the] linkage now exists" between the regulation and the statute. *Id.* at 980. This duty "is even more pressing" when the original policy, as in the case of EPA's HTF lead default value, was never the subject of public notice and comment. *Bechtel v. Federal Communications Commission*, 957 F.2d 873, 881 (D.C. Cir.), *cert. denied,* 506 U.S. 816 (1992).

Regardless of any justification that may have existed in 1990, sufficient data and expert opinion exist today so that the presence of lead must be evaluated in the same way as other hazardous substances. Thus, "[e]ven assuming that the rules in question initially were justified, . . . it is plain that justification has long since evaporated." *Geller*, 610 F.2d at 980 (D.C. Cir. 1979).

CONCLUSION

For the foregoing reasons, EPA's current HTF value is not supportable given the current knowledge about the toxicity of lead and EPA's improved tools to evaluate health risks associated with lead. As recalculation of the RfD for lead results in a HTF value for lead of no greater than 1,000, EPA should immediately initiate rulemaking to make this revision.

Respectfully submitted,

Timothy J. Lafond
Chairman,
BCI Environmental Committee

Attachments